

Amendment and Response

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Serial No.: 10/718,359

Confirmation No.: 3660

Filed: November 20, 2003

For: NaCT AS A TARGET FOR LIFESPAN EXPANSION AND WEIGHT REDUCTION**Remarks**

The Office Action mailed October 18, 2007, has been received and reviewed. Claims 12, 20, 57-59, and 76-78 having been amended, claims 1-11, 14-19, 22-26, 29-49, 51-56, 60-75, 80, and 81 having been canceled, without prejudice, the pending claims are claims 12, 13, 20, 21, 27, 28, 50, 57-59, 76-79, 82, and 83. Claims 21, 57-59, 76, and 77 being withdrawn from examination, as drawn to non-elected inventions, the claims currently under examination are 12, 13, 20, 27, 28, 50, 78, 79, 82, and 83. Reconsideration and withdrawal of the rejections are respectfully requested.

Restriction Requirement

As amended in the Amendment and Response filed August 3, 2007, claim 21 is drawn to an isolated polypeptide. Applicants submit that claim 21 properly belongs to Group II (an isolated polypeptide), elected in response to the Restriction Requirement mailed October 10, 2006, and presently under examination. The rejoinder and examination of claim 21 is requested. Further, the rejoinder and examination of method claims 57-59, 77, and 78 is requested.

The 35 U.S.C. §112, Second Paragraph, Rejection

The Examiner rejected claims 12, 13, 20, 27, 28, 50, 78, 79, 82, and 83 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner asserted that the metes and bounds of the recitation "stringent hybridization conditions" in claims 12 and 78 is unclear. This rejection is traversed.

As amended, claims 12 and 78 recite "wherein stringent hybridization conditions are 6X SSC, 5X Denhardt, 0.5% sodium dodecyl sulfate (SDS), and 100 µg/ml fragmented and denatured salmon sperm DNA hybridized overnight at 65°C and washed in 2X SSC, 0.1% SDS at least one time at room temperature for about 10 minutes followed by at least one wash at 65°C

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for about 15 minutes followed by at least one wash in 0.2X SSC, 0.1% SDS at room temperature for at least 3 to 5 minutes." Support for this claim amendment is found on page 10, lines 4-11 of the specification. Applicants submit that the metes and bounds of amended claims 12 and 78 (and dependent claims 13 and 79) are clear. The reconsideration and withdrawal of this rejection of under 35 U.S.C. §112, second paragraph, is respectfully requested.

Only claim 13 depends from claim 12 and only claim 79 depends from claim 78. Thus, Applicants do not understand the inclusion of claims 20, 27, 28, 50, 82, and 83 in this rejection, based on the recitation "stringent hybridization." Clarification is requested.

The 35 U.S.C. §112, First Paragraph, Written Description Rejection

The Examiner rejected claims 12, 13, 20, 27, 28, and 78 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is traversed.

The Examiner asserted that the specification teaches only a single species of NaCT transporter, the human NaCT transporter (SEQ ID NO:6), and that the function of this NaCT transporter is unidentified (page 3, Office Action mailed October 18, 2007). Applicants adamantly, yet respectfully, submit that this assertion is incorrect. The teachings of the specification are not limited to only the human NaCT transporter (SEQ ID NO:6). Rather, the specification teaches the amino acid sequence of the NaCT transporters of a representative sampling of species, including human (SEQ ID NO:6), rat (SEQ ID NO:4), mouse (SEQ ID NO:10), the nematode *C. elegans* (SEQ ID NO:8), and zebrafish (SEQ ID NO:12) (see, for example, page 131 of the specification). Further, the specification teaches that the NaCT transporter from each of these species (human, rat, mouse, *C. elegans*, and zebrafish) is functional, capable of the Na⁺-dependent transmembrane transport of citrate (see, for example page 72, lines 10-11, page 54, lines 8-18, page 102, line 26-page 103, line, page 83, lines 6-13, and page 118, lines 20-24 of the specification, respectively). Applicants submit that the

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specification describes a representative sampling of the claimed polypeptides and provides adequate written description to reasonably convey to one of skill in the art that the inventors, at the time of the invention, had possession of the claimed invention. Further, Applicants do not understand the inclusion of claim 13 ("wherein the polypeptide comprises SEQ ID NO:6") in the present rejection.

Claims 12, 13, and 78 are drawn to polypeptides encoded by a polynucleotide that hybridizes to SEQ ID NO:5 under stringent hybridization conditions (including 6X SSC and 65 degrees Celsius), wherein the polypeptide exhibits a specific function (the Na⁺-dependent transmembrane transport of citrate). Applicants submit that the specification provides an adequate written description for the polypeptides of claims 12, 13, and 78. The specification teaches at least a single species, that is, SEQ ID NO:6, a polypeptide encoded by a polynucleotide that hybridizes to SEQ ID NO:5 under stringent hybridization conditions. Applicants submit "that hybridization techniques using a known DNA as a probe under highly stringent conditions [6X SSC and 65 degrees Celsius] were conventional at the time of filing" (see Example 6, page 36 of the USPTO's "Revised Interim Written Description Guidelines Training Materials," available at www.uspto.gov/web/offices/pac/writtendesc.pdf). Further, Applicants submit that "a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention" (see Example 6, pages 36-37 of USPTO's "Revised Interim Written Description Guidelines Training Materials," available at www.uspto.gov/web/offices/pac/writtendesc.pdf). Applicants respectfully submit that the teachings of the specification, in view of the high level of skill in the art, adequately describe the polypeptides of claims 12, 13, and 78. Reconsideration and withdrawal of this rejection under 35 U.S.C. §112, first paragraph, is requested.

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To expedite prosecution, independent claim 20 has been amended to recite "comprising an amino acid sequence having at least 95% identity to SEQ ID NO:6." Applicants reserve the right to continue prosecution of canceled subject matter in related applications. As acknowledged by the Examiner, Applicants submit that the specification provides adequate written description for claims 20, 21, 27, and 28, drawn to polypeptides comprising at least 95% identity to SEQ ID NO:6.

In view of the above discussion, reconsideration and withdrawal of this written description rejection of claims 12, 13, 20, 27, 28, and 78 under 35 U.S.C. §112, first paragraph, is requested.

The 35 U.S.C. §112, First Paragraph, Enablement Rejection

The Examiner rejected claims 12, 13, 20, 27, 28, and 78 under 35 U.S.C. §112, first paragraph, alleging that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is traversed.

Specifically, the Examiner asserted the specification "does not reasonably provide enablement for a polypeptide variant encoded by a hybridizing nucleic acid [or a] polypeptide which has less than 95% identity to SEQ ID NO:6" (page 4, Office Action mailed October 18, 2007). Applicants disagree and submit that the specification provides adequate guidance to allow one of skill in the art to make and use the claimed polypeptides, without undue experimentation. Further, based on the Examiner's assertion, Applicants do not understand the inclusion of claim 13 ("wherein the polypeptide comprises SEQ ID NO:6") in the present rejection.

Claims 12, 13, and 78 are drawn to isolated polypeptides "encoded by a polynucleotide that hybridizes to SEQ ID NO:5 under stringent hybridization conditions, wherein the polypeptide is capable of Na⁺-dependent transmembrane transport of citrate" (SEQ ID NO:5 is the nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:6). The

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Examiner is directed to, for example, page 74, lines 2-14 and page 10, lines 4-11 of the specification for guidance on obtaining polynucleotides that hybridizes to SEQ ID NO:5 under stringent hybridization conditions. The Examiner is further directed to, for example, page 74, line 28 to page 75, line 20 and page 77, lines 1-18 of the specification for guidance on identifying polynucleotides encoding polypeptides capable of Na⁺-dependent transmembrane transport of citrate. The level of skill in the art pertaining to hybridization and the expression of polynucleotides is very high. Applicants submit that the teachings of the specification combined with the high level of skill in art provide adequate guidance to allow one of skill in the art to make and use the polypeptides of claims 12, 13, and 78 without undue experimentation.

To expedite prosecution, independent claim 20 has been amended to recite "comprising an amino acid sequence having at least 95% identity to SEQ ID NO:6." Applicants reserve the right to continue prosecution of canceled subject matter in related applications. As acknowledged by the Examiner, Applicants submit that the specification fully enables claims 20, 21, 27, and 28, drawn to polypeptides comprising at least 95% identity to SEQ ID NO:6.

In view of the above discussion, reconsideration and withdrawal of this enablement rejection of claims 12, 13, 20, 27, 28, and 78 under 35 U.S.C. §112, first paragraph, is requested.

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Summary

It is respectfully submitted that the pending claims 12, 13, 20, 21, 27, 28, 50, 57-59, 76-79, 82, and 83 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 18 day of March, 2008, at 1:40 pm (Central Time).

By:

Sandy Truehart

Name:

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